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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NICHOLAS V. PERRICONE and CHIM POTINI

Appeal 2010-004708
Application 10/750,390
Technology Center 1600

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and MELANIE L. McCOLLUM, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for lack of written description, indefiniteness and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The following claim is representative and reads as follows:

1. A method of formulating a topical insulin composition comprising: preparing a non-liposome multilamellar liquid crystal phosphatidylcholine non-polar carrier for topical administration; and mixing an insulin solution into said carrier to entrap said insulin within said carrier, wherein said insulin is stabilized at room temperature.

Cited References

The Examiner relies on the following prior art references:

Amselem et al.	US 5,662,932	Sep. 2, 1997
Lynch et al.	US 2002/0153509 A1	Oct. 24, 2002
Hansen et al.	US 4,614,730	Sep. 30,1986
Patel et al.	US 6,294,192 B1	Sep. 25, 2001
Chaiyawat et al.	US 6,538,061 B2	Mar. 25,2003
Brieva et al.	US 5,985,298	Nov. 16,1999

Grounds of Rejection

1. Claims 1-6, 8 and 11-16 are rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement.

2. Claims 1-6, 8 and 11-16 are rejected under 35 U.S.C. § 112, second paragraph for claim indefiniteness.

3. Claims 1-6, 8 and 11-16 are rejected under 35 U.S.C. § 103(a) for obviousness over Amselem or Lynch in view of Hansen, Patel, Chaiyawat and Brieva.

FINDINGS OF FACT

1. The Specification states that, "[p]hosphatidylcholine is used as a carrier for the formulation of stabilized insulin compositions in the practice of this invention." (Spec.3, ¶ 0008.)

2. The Specification states that "[s]tabilized insulin compositions formulated in accordance with the present invention are non-polar and formulated to contain polypeptides and macromolecules soluble in phosphatidylcholine." (Id. at ¶ 9.)

3. The Specification states that the "composition may be in liquid crystal phase, with the PPC-enriched phosphatidylcholine loosely arranged in multilamellar fashion, with the polypeptide or macromolecule being bonded and entrapped within the lipid bilayers formed therein." (Id. at 5, ¶13.)

4. The Specification states that the "[s]tabilized insulin compositions are generally formulated by preparing a carrier having a phosphatidylcholine component, preferably including a PPC-enriched phosphatidylcholine material with the trade name NAT 8729 … and at least one polyglycol … a surfactant...silicone fluids" and water. (Spec. 5-6, ¶ 16.)

5. The Specification provides a working example of a composition comprising a phosphatidylcholine carrier and insulin stating that

[s]table insulin compositions were formulated by first preparing a base solution. Polyglycol E200 (PEG-200) (50% w/w) was weighed and polyglycol E400 (PEG-400) (5% w/w) was added to the same container to obtain the desired weight, (both obtained from Dow Corning). PEG-200 and PEG-400 were lightning mixed at 38-40° C with IKA model RW20 using a

disintegration head impeller slowly at 800 rpm (speed 1), yielding PEG-200/PEG-400 solution. A PPC-enriched phosphatidylcholine material denoted NAT 8729 containing 80.6% PPC-enriched phosphatidylcholine and 4.9% lysophosphatidylcholine was obtained from Rhône-Poulenc. NAT 8729 (45% w/w) was shaved and added to PEG-200/PEG-400 solution, covered and mixed, with temperature not exceeding 40°C, until a clear, viscous amber solution with no sediments or separations resulted. The mixing time was approximately five hours. (Spec. 6-7, ¶ 17.)

6. The Specification states that a "drug delivery composition formulated with somatotropin was formulated in one trial with 85% phosphatidylcholine to which lipoic acid and ascorbyl palmitate were added." (Spec. 8, ¶ 22.)

Discussion

1. Claims 1-6, 8 and 11-16 are rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement.
2. Claims 1-6, 8 and 11-16 are rejected under 35 U.S.C. § 112, second paragraph for claim indefiniteness.

ISSUE

The Examiner argues that the phrase "'non-liposome multilamellar crystal non-polar phosphatidylcholine' was not described in the specification as filed." (Ans. 3.) The Examiner argues that the carrier contains both polar phosphatidylcholine and polar polyglycols.

Appellants argue that the claim does not state "non-polar phosphatidylcholine", but instead recites a "non-polar carrier." (See App. Br. 6.) Appellants argue that although the term '"non-liposomal' is not specifically referred to in the specification, a person of average skill in the art would have known that a multilamellar liquid crystal is not a liposome." (App. Br. 7.)

The issues are: Does the Specification as filed support the claim phrase "non-liposome multilamellar liquid crystal phosphatidylcholine non-polar carrier"? Is the phrase "non-polar carrier" indefinite?

ANALYSIS

Appellants argue that the claim "does not state 'non-polar phosphatidylcholine', but instead recites a 'non-polar carrier.'" (Id. at 6.) Appellants argue that "[a]lthough the term 'non-liposomal' is not specifically referred to in the specification, a person of average skill in the art would have known that a multilamellar liquid crystal is not a liposome." (Id. at 7.)

We are not persuaded by Appellants' arguments. The Specification does not expressly define the phrase "non-liposomal multilamellar liquid crystal phosphatidylcholine non-polar carrier." The Specification does not expressly state that the carrier can be made up solely of phosphatidylcholine. The Specification does not identify the specific steps of treating the pure phosphatidylcholine that cause it to form a non-liposomal multilamellar liquid crystal phosphatidylcholine non-polar carrier. Nor does the

Specification state whether other components or particular mixing conditions are required to cause phosphatidylcholine to form a non-liposomal multilamellar liquid crystal phosphatidylcholine non-polar carrier.

The Specification provides two working examples of the claimed composition, neither of which describes the carrier as pure phosphatidylcholine. One is described as containing a drug in 85% phosphatidylcholine, with two antioxidants added, but with no description of additional carrier components or treatment conditions that caused the phosphatidylcholine to form a non-liposomal multilamellar liquid crystal phosphatidylcholine non-polar carrier. (See Spec. 8, ¶8.)

The other exemplary composition described in the Specification contains a commercially available phosphatidylcholine.

> Polyglycol E200 (PEG-200) (50% w/w) was weighed and polyglycol E400 (PEG-400) (5% w/w) was added to the same container to obtain the desired weight, (both obtained from Dow Corning). PEG-200 and PEG-400 were lightning mixed at 38-40° C with IKA model RW20 using a disintegration head impeller slowly at 800 rpm (speed 1), yielding PEG-200/PEG-400 solution. A PPC-enriched phosphatidylcholine material denoted NAT 8729 containing 80.6% PPC-enriched phosphatidylcholine and 4.9% lysophosphatidylcholine was obtained from Rhône-Poulenc. NAT 8729 (45% w/w) was shaved and added toPEG-200/PEG-400 solution, covered and mixed, with temperature not exceeding 40°C, until a clear, viscous amber solution with no sediments or separations resulted.

(Spec. 6, ¶ 6.)

The Specification does not describe the function of any of these components in the exemplary composition or disclose whether some or all of

them are necessary to make a form a non-liposomal multilamellar liquid crystal phosphatidylcholine non-polar carrier using phosphatidylcholine.

Even when the claims are read in light of the Specification, therefore, we are unable to determine whether the claimed composition can contain only phosphatidylcholine and a drug, or whether other components are required in order for the phosphatidylcholine carrier to take on the claimed structure. Since the scope of the claims is unclear even when they are read in light of the Specification, we agree with the Examiner that the written description does not support the pending claim scope and that the claims are indefinite, although not simply because the claims recite a "non-polar carrier" comprising phosphatidycholine. For the reasons given with respect to the lack of written description rejection, the indefiniteness rejection is also affirmed. Because our analysis differs from that of the Examiner we designate our decision a new ground of rejection.

3. Claims 1-6, 8 and 11-16 are rejected under 35 U.S.C. § 103(a) for obviousness over Amselem or Lynch in view of Hansen, Patel, Chaiyawat and Brieva.

When claims are indefinite, rejecting under 103 based on speculation and assumptions is legal error. In re Steele, 305 F.2d 859, 862 (CCPA 1962).

Thus, we are unable to reach the obviousness rejection because of claim indefiniteness.

CONCLUSION OF LAW

The written description and indefiniteness rejections are affirmed. We are unable to reach the obviousness rejection because of claim indefiniteness.

This decision also contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .
>
> (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . .

AFFIRMED, 37 C.F.R. § 41.50(b)

alw